IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex rel.* DIANA ZALDONIS, Plaintiffs, v. UNIVERSITY OF PITTSBURGH MEDICAL CENTER, UNIVERSITY OF PITTSBURGH PHYSICIANS, UNIVERSITY OF PITTSBURGH OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION, Defendants.	2:19-CV-01220-CCW

MEMORANDUM OPINION AND ORDER

Before the Court is a Motion to Dismiss under Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6) filed jointly by Defendant University of Pittsburgh Medical Center ("UPMC") and Defendant University of Pittsburgh Physicians ("UPP"). *See* ECF No. 23. Because the Court agrees with UPMC and UPP that Relator Diana Zaldonis has failed to adequately plead materiality, as required under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, the Motion will be GRANTED. Counts I and II of the Complaint will be dismissed without prejudice and Ms. Zaldonis will be given leave to file an amended complaint.

I. Background

A. Procedural History

Ms. Zaldonis filed her sealed Complaint in this *qui tam* action on September 24, 2019. *See* ECF No. 1; *see also* 31 U.S.C. § 3730(b) (providing for actions by private persons under the False Claims Act). After the United States declined to intervene, ECF No. 5, the Complaint was unsealed on June 5, 2020. *See* ECF Nos. 6–7. Defendant University of Pittsburgh filed an answer, *see* ECF

No. 25, while UPMC and UPP together moved to dismiss. *See* ECF No. 23. The Court held oral argument on UPMC and UPP's Motion on March 5, 2021. *See* ECF No. 40.

B. The Alleged FCA Violations

The Complaint sets out four causes of action, only two of which are brought against UPMC and UPP and are therefore relevant to the Motion. According to Ms. Zaldonis, UPMC and UPP, in violation of 31 U.S.C. § 3729(a)(1)(A)–(B), knowingly presented false claims for payment to government payors (Count I) and made or used false records or statements material to those claims for payment (Count II).[1] *See* ECF No. 1 at ¶¶ 131–138. In broad strokes, and as relevant to UPMC and UPP's Motion to Dismiss, the Complaint alleges as follows:

> [B]etween at least 2013 and the present, attending surgeons in the UPMC Department of Cardiothoracic Surgery, including but not limited to doctors James Luketich and Pablo Sanchez, improperly delegated the responsibility to obtain patients' consent for surgical procedures to residents, fellows, nurse practitioners, and physician assistants, in violation of federal and state law as well as UPMC policy. These cardiothoracic surgeons often signed a consent form falsely certifying that they had explained to the patient all of the information in the consent form, when, in fact, they had not.

ECF No. 1 at ¶ 7. UPMC and UPP would then bill government payors—specifically the U.S. Centers for Medicare & Medicaid Services ("CMS"), the Defense Health Agency (administrator of TRICARE), and the Veterans Health Administration Office of Community Care (administrator of CHAMPVA)—"for hospital costs associated with cardiothoracic surgeries…as well as for certain costs associated with the clinical trials for medical devices used during [lung] transplants" where the primary surgeon allegedly delegated the task of obtaining patient consent to another practitioner. *See id.* at ¶¶ 10–11. According to Ms. Zaldonis, this practice violated the False

[1] The remaining claims in the Complaint, Counts III and IV, relate to Defendant University of Pittsburgh's alleged wrongful termination of Ms. Zaldonis after she reported the alleged issues with UPMC's and UPP's informed consent practices. *See* ECF No. 1 at ¶¶ 122–130, 139–145.

Claims Act, 31 U.S.C. § 3729 *et seq.*, because "[t]hese claims [for payment] falsely certified compliance with CMS regulations, including those requiring them to obtain their patients' informed consent properly prior to surgery," which in turn "caused Medicare and other government payors to remit funds to UPMC and UPP." ECF No. 1 at ¶ 104.

Because the FCA is concerned with "fraud, not medical malpractice," *Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989, 2004 (2016), Ms. Zaldonis' claims against UPMC and UPP hinge on the allegedly false certifications made by UPMC and UPP in connection with claims for payment submitted to government payors. According to the Complaint, UPMC bills government payors using CMS Form 1450 (or its electronic equivalent, Form 837I), while UPP uses Form 1500 (or its electronic equivalent, Form 837P). *See* ECF No. 1 at ¶ 100. UPMC and UPP use these forms when submitting claims to CMS (for Medicare and Medicaid), the Defense Health Agency (for TRICARE), and the Veterans Health Administration Office of Community Care (for CHAMPVA). *See id*. These forms contain the following relevant certification language:

> Form 1450: "Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. The submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts."
>
> Form 1500: "[T]his claim…complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral Law (commonly known as the Stark Law)."

See ECF No. 1 at ¶¶ 100–102. In addition to the Form 1450 and Form 1500 certifications accompanying every request for payment, Ms. Zaldonis also points out that UPMC and UPP certified compliance "with applicable laws and regulations at the time of enrollment in Medicare." *See id.* at ¶ 103. Form 855A, Medicare's Enrollment Application, which providers like UPMC and UPP submit at the time they enroll in the program, requires providers to certify, in relevant

part, that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare." *See id.*

C. The Motion to Dismiss

UPMC and UPP advance three arguments in support of their Motion to Dismiss. First, they contend that the Complaint fails to state a claim because it fails to identify an applicable regulation prohibiting a patient's principal surgeon from delegating the informed consent process to other practitioners. *See* ECF No. 24 at 13. Next, UPMC and UPP argue that, even if delegation of the informed consent process is prohibited, as alleged here, the Complaint fails to plead either an express or implied false certification claim under the FCA. *See id.* at 18; *see also* ECF No. 34 at 11. In short, UPMC and UPP assert that because the certifications at issue do not make any representations about the consent process used, do not specifically affirm compliance with any consent-related regulation, and fail to adequately plead materiality, the Complaint fails to state either type of false certification claim. Finally, UPMC Defendants maintain that the Complaint satisfies neither Fed. R. Civ. P. Rule 8(a)'s plausibility requirement nor Rule 9(b)'s particularity requirement. *See* ECF No. 24 at 25.

II. Standard of Review

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a claim. In reviewing a motion to dismiss, the court accepts as true a complaint's factual allegations and views them in the light most favorable to the plaintiff. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d. Cir. 2008). Although a complaint need not contain detailed factual allegations to survive a motion to dismiss, it cannot rest on mere labels and conclusions. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is, "a formulaic recitation of the elements of a cause of action will not do."

Id. Accordingly, "[f]actual allegations must be enough to raise a right to relief above the speculative level," *id*., and be "sufficient to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than the sheer possibility that a defendant has acted unlawfully." *Id*. (quoting Twombly, 550 U.S. at 556).

The United States Court of Appeals for the Third Circuit has established a three-step process for district courts to follow in analyzing a Rule 12(b)(6) motion:

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Finally, "where there are well-pleaded allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief."

Burtch v. Milberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011) (quoting *Santiago v. Warminster Twp*., 629 F.3d 121, 130 (3d Cir. 2010)).

III. Legal Framework – False Claims Act

"The False Claims Act is meant 'to reach all types of fraud . . . that might result in financial loss to the Government.'" *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 486 (3d Cir. 2017) (quoting *Cook Cty. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003)). In relevant part, the FCA imposes liability on any person who: "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). Applying these provisions, the Third Circuit has held that four elements are necessary to state a claim for violation of the FCA: "falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487.

Claims for payment which violate the FCA fall into two broad categories: factually false claims and legally false claims. A factually false claim is one in which "the claimant misrepresents what goods or services that it provided to the Government." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (citing *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc*., 543 F.3d 1211, 1217 (10th Cir. 2008)). A legally false claim, on the other hand, is premised on a "false certification" theory of liability, and occurs when "the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* (citing *Conner*, 543 F.3d at 1217). Legally false claims are further categorized as being based on either express or implied false certifications. *Id.*

"Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *Id.* (citing *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 441 (3d Cir. 2004)). The "implied false certification" theory, on the other hand, holds that where "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Escobar*, 136 S.Ct. at 1999.

In either case, however, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Id.* at 2002. According to the Supreme Court, "[t]he materiality standard is demanding. The False Claims Act is not 'an all-purpose anti-fraud statute,'…or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

Under the FCA, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Thus, "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, at 2002 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)). As such, "a material misrepresentation is one that 'goes to the very essence of the bargain.'" *Petratos*, 855 F.3d at 489 (quoting *Escobar*, 136 S.Ct. at 2003 n.5).

IV. Discussion

Whether read as asserting express or implied false certification claims, the Court concludes that Ms. Zaldonis' Complaint fails to adequately plead materiality; i.e., that the federal government would have refused to pay for certain surgeries had it known that UPMC and UPP physicians were delegating the task of obtaining patient informed consent to other practitioners.[2] While the Court stops short of concluding, as suggested by UPMC and UPP's counsel at oral argument, that informed consent violations *cannot* be material for FCA purposes, *see* Hr'g Tr. at 14:1–17, the Court finds that Ms. Zaldonis' Complaint as currently pled fails to surmount the "rigorous" materiality threshold required to state a claim under the FCA. *See Escobar*, 136 S.Ct. at 2002.

The Complaint cites regulations applicable to Medicare, Medicaid, and CHAMPVA which relate to patient rights. *See* ECF No. 1 at ¶¶ 36, 37–39; *see also* 42 C.F.R. § 482.13(b) (CMS

[2] Neither the Complaint, Relator's briefing, or the oral argument made clear whether or not Plaintiff is proceeding on an implied certification theory. *See generally* ECF No. 1; *see also* ECF No. 30 at 17–18 (arguing that "Defendants wrongly posit that Relator's Complaint alleges only an implied false certification theory…ignoring the Complaint's references to express certifications," but offering only argument on express false certification); Hr'g. Tr. at 5:2–4, 7:18–9:10 (discussing express false certification). Rather, Ms. Zaldonis' arguments appear to focus on express false certification. However, Defendant addresses both theories in its briefing. *See* ECF No. 24 at 18; ECF No. 34 at 11. The Court's decision here does not rest on the distinction between the two theories.

"Condition of participation: Patient's rights"); 42 C.F.R. § 482.24(c)(4)(v) (CMS "Condition of participation: medical record services"); 38 C.F.R. § 17.32(c)(6) (VA regulation covering "Informed consent and advance care planning").[3] For example, Medicare conditions of participation provide that "[t]he patient has the right to participate in the development and implementation of his or her plan of care" and that

> The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.

42 C.F.R. § 482.13(b). From this baseline statement of patient rights flow certain other Medicare conditions of participation relevant to Ms. Zaldonis' claims. First, 42 C.F.R. § 482.24(c)(4)(v) requires that a patient's medical record contain "[p]roperly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent." Second, § 482.51(b)(2), related to surgical services, requires that "[a] properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies." Importantly, however, neither § 482.24(c)(4)(v) nor § 482.51(b)(2) (nor any other Medicare condition of participation of which the Court is aware) defines or prescribes what it means for an informed consent form to be "properly executed." *See* ECF No. 30 at 9.

Attempting to fill this gap, Ms. Zaldonis highlights the phrase "specified by the medical staff, or by Federal or State law if applicable" from § 482.24(c)(4)(v). She also points to interpretive guidance from CMS' State Operations Manual, which states that "[a]n informed consent form, in order to be properly executed, must be consistent with hospital policies as well

[3] The Complaint does not cite to any TRICARE-specific regulations related to informed consent. *See* ECF No. 1 at ¶ 36.

as applicable State and Federal law or regulation." *See* ECF No. 30 at 10; ECF No. 34-1 at 4. Based on this language from the regulation and the CMS Manual, Ms. Zaldonis argues that the formal requirements for a properly executed patient informed consent form are supplied by state law and hospital policy. *See* ECF No. 30 at 10; HT at 22:19–23:6. And, she notes, under Pennsylvania medical malpractice law, obtaining patient informed consent prior to surgery is a non-delegable duty that rests with the lead physician. *See* ECF No. 30 at 11; HT at 23:2–6; *see also Shinal v. Toms*, 162 A.3d 429, 455 (Pa. 2017). UPMC policy, reflecting *Shinal*, arguably does not permit delegation either. *See* ECF No. 1 at ¶ 6 (quoting UPMC patient bill of rights, which states, "[e]xcept for emergencies, a patient's physician must obtain the necessary informed consent prior to the start of any procedure or treatment."). Therefore, Ms. Zaldonis reasons, a physician who delegates obtaining informed consent to another practitioner violates applicable federal regulations (like 42 C.F.R. § 482.24(c)(4)(v), which according to Ms. Zaldonis incorporates state law and hospital policy), thereby rendering false any request for payment that certifies compliance with applicable rules and regulations.

We need not decide today whether Ms. Zaldonis' chain of reasoning, outlined above, is correct. Assuming that it is, it would establish falsity, but would not overcome the hurdle of demonstrating materiality. That is, neither the conditions of participation, nor CMS' State Operations Manual, nor the Pennsylvania Supreme Court's decision in *Shinal* says anything, one way or the other, about whether knowing that a physician delegated obtaining informed consent to another practitioner would have any effect on the government's decision to pay a claim.

In attempting to establish materiality, Ms. Zaldonis posits that materiality can be determined by reference to three considerations, each of which she contends the Complaint adequately addresses: "whether compliance with a statute is a condition of payment; whether the

violation goes to 'the essence of the bargain' or is 'minor or insubstantial'; and whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations." ECF No. 30 at 19 (quoting *U.S. ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017) (citing *Escobar*, 136 S. Ct. at 2003)). Ms. Zaldonis asserts that (1) informed consent is a "condition of payment" under Medicare regulations; (2) it is a "core patient's right" and therefore is "central to the bargain;" and (3) certain administrative law cases show the government has excluded providers from participation in Medicare for failure to properly obtain informed consent. *See* ECF No. 30 at 19–21.

Ms. Zaldonis' arguments, here, are lacking. First, informed consent appears in regulations touching on Medicare conditions of *participation*, not *payment*. *Compare* 42 C.F.R., Part 424 *with* 42 C.F.R., Part 482. The difference is important: although the Supreme Court in *Escobar* recognized that violation of a condition of participation may be sufficiently important to be material for FCA purposes, it is not necessarily so. And, as other courts have recognized, the government has a robust administrative oversight scheme designed to maintain provider standards, like informed consent processes. *See, e.g., U.S. ex rel. Conner v. Salina Reg'l Health Ctr. Inc.*, 543 F.3d 1211, 1220–21 (10th Cir. 2008) (describing hospital survey and plan of correction scheme used to maintain compliance with conditions of participation). The upshot of this administrative oversight system is that, contrary to Ms. Zaldonis' assertion, where a provider is found to be noncompliant, the government does not immediately suspend billing privileges or terminate program participation; rather, the provider is given an opportunity to implement corrective action before such drastic measures are taken. *See id*; *see also* 42 C.F.R. § 488.28. Second, and relatedly, although 42 C.F.R. 482.24(c)(4)(v) identifies informed consent as a condition of participation, the administrative cases cited by Ms. Zaldonis do not stand for the proposition that the government

refuses to pay claims where the task of obtaining informed consent was delegated by a patient's principal surgeon; rather, at most, these cases reflect the fact that the government may penalize a provider or terminate a provider's ability to participate in Medicare after repeated failures to obtain patient consent at all prior to treatment. *See* ECF No. 24 at 23–25 (summarizing administrative cases cited in Complaint).

Even if we were to credit Ms. Zaldonis' legal arguments in full, however, a fundamental problem with her Complaint is that, with two exceptions discussed below, she fails to allege that UPMC and UPP's patients were not provided with important information about their care. Rather, she asserts only that the (allegedly) wrong practitioner provided informed consent information. Ms. Zaldonis, both in her papers and at oral argument, relies on *U.S. ex rel. Wollman v. Gen. Hosp. Corp.*, 394 F.Supp.3d 174 (D.Mass. 2019), which found, in part, that a relator had adequately pled an FCA claim related to deficient informed consent. *See* ECF No. 30 at 4; Hr'g. Tr. at 47:18–49:20. But *Wolman* is distinguishable, and the comparison to the allegations here highlights the shortcomings of Ms. Zaldonis' Complaint: to the extent *Wollman* stands for the proposition that an informed consent violation can form the basis of an FCA claim, it says nothing about delegation. In *Wollman*, surgeons at a teaching hospital scheduled concurrent and/or overlapping surgeries. *See id.* at 179. In addition to other violations—for example, the surgeons in question allegedly took no part in some of the procedures, contrary to the billing requirements for such surgeries—the informed consent forms signed by patients prior to surgeries failed to inform the patients that their primary surgeon was scheduled for overlapping/concurrent procedures and that important parts of their surgery would be performed by other doctors. *See id.* at 184. In short, the informed consent violation alleged in *Wollman* was not that the "wrong" practitioner obtained patient consent but that the patients were not provided with important information about their surgery.

Unlike *Wollman*, here there is no allegation that any of the patients for whom the informed consent process was delegated by the lead surgeon to another practitioner did not receive adequate information. Furthermore, the two exceptions mentioned above are not alleged to have involved delegation at all.

First, Ms. Zaldonis alleges that Dr. Thomas Gleason totally failed to obtain patient consent prior to surgery and then directed a resident to enter a note in the records falsely indicating that Dr. Gleason had, in fact, obtained consent. *See* ECF No. 1 at ¶ 95. According to the Complaint, the resident reported this deviation from protocol to Dr. Luketich, who said he would "look into it." *Id.* Viewing these allegations in the light most favorable to Ms. Zaldonis, the Court cannot conclude that this apparently isolated failure to obtain informed consent prior to surgery is sufficient to state an FCA claim on its own. Indeed, the allegation fails to identify whether the patient was the beneficiary of any government healthcare program, like Medicare or TRICARE, which on its own is fatal to this alleged incident supporting an FCA claim. *See id.* Furthermore, even if the patient was such a beneficiary, an isolated incident of alleged medical malpractice is not sufficient to meet the materiality showing required under *Escobar*. *See* 136 S.Ct. at 2004 ("We emphasize, however, that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations. This case centers on allegations of fraud, not medical malpractice.")

Second, the Complaint alleges, based on state court filings, that Dr. Sanchez failed to obtain consent from patient Bernadette Fedorka for a lung transplant operation. *See id.* at ¶¶ 117–21. But, importantly, the Fedorka allegations fail to describe the nature of the alleged informed consent violation and give no indication that Dr. Sanchez delegated the task of obtaining consent to another practitioner. *See id.* Indeed, what these allegations appear to claim is that consent was improperly

obtained from Ms. Fedorka's husband, despite Ms. Fedorka being capable of providing such consent at the time of her surgery. *See id.* In sum, neither the incident involving Dr. Gleason nor the incident involving Ms. Fedorka appears to have involved the alleged delegation "scheme" described in the Complaint, and, importantly, neither set of allegations goes beyond describing potential medical malpractice to assert that a fraud was committed against the government.

According to the Supreme Court in *Escobar,* "[t]he materiality standard is demanding. The False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." 136 S.Ct. at 2003 (quoting *Allison Engine,* 553 U. S. at 672). Applying *Escobar*, the Third Circuit has noted that "a material misrepresentation is one that goes 'to the very essence of the bargain.'" *Petratos,* 855 F.3d 489 (quoting *Escobar,* 136 S.Ct. at 2003 n.5). While the Court agrees with Ms. Zaldonis that informed consent is an important part of medical care, we are not convinced that she has met her burden to show that the particular delegation "scheme" she alleges here—to the extent it is a violation of applicable regulations at all—would cause the government to deny payment. Accordingly, Ms. Zaldonis' claims in Counts I and II will be dismissed.

V. Conclusion

For the foregoing reasons, the Motion to Dismiss filed by Defendants UPMC and UPP is hereby GRANTED and Counts I and II of the Complaint are hereby DISMISSED WITHOUT PREJUDICE. Ms. Zaldonis may file an amended complaint to attempt to cure the deficiencies identified herein, on or before May 28, 2021.

DATED this 14th day of May, 2021.

BY THE COURT:

/s/ Christy Criswell Wiegand
CHRISTY CRISWELL WIEGAND
United States District Judge

cc (via ECF email notification):

All Counsel of Record